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Application No. 09/147,036
Reply to Office Action of November 3, 2004
Amendment Dated March 3, 2005

REMARKS

Claims 1-3, 9-15, 19, 41, 43-53, and 55-59 were pending and under consideration in this application. By this Amendment, Applicants have canceled claims 2-8, 54, and 59 without prejudice to Applicants' right to present the subject matter of these claims in a future continuation or divisional application. Applicants have amended claims 1, 15, 41, 55, and 57 in response to the Examiner's concerns set forth in the November 3, 2004 Final Office Action. Support for the claim amendments can be found throughout the specification and claims as originally filed. This Amendment does not introduce any new matter and thus, its entry is respectfully requested. Upon entry of the present Amendment, claims 1, 9-15, 19, 41, 43-53, and 55-58 will be pending and under examination.

The November 3, 2004 Final Office Action**Rejections Withdrawn**

Applicants acknowledge and appreciate the withdrawal of the objections and indefiniteness rejections set forth in the previous Office Action.

Rejections Under 35 U.S.C. §112, first paragraph

The Examiner has maintained the rejection of claims 1-3, 9-15, 19, 41, 43-53, and 55-59 under 35 U.S.C. §112, first paragraph, as allegedly lacking both adequate written description and full enablement, because no biological deposit has been made of record. Applicants note that the

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Examiner has again indicated that the claims are enabled for a process for presenting passenger peptides or polypeptides on the surface of a gram-negative host bacteria in which the transporter domain is an AIDA protein of E.coli, but, in the Examiner's opinion, not for processes in which the transporter is a variant. In that regard, the Examiner has maintained that there is not sufficient guidance in the specification as to what specific changes can be made to the AIDA protein which would allow the resulting variant to retain biological function.

The Examiner also rejected claims 1-3, 9-15, 19, 41, 43-53, and 55-59 under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description in their recitation of a "variant having a homology of at least 80% of the AIDA-1 autotransporter domain in at least its β -sheet region." The Examiner has asserted that this clause represents new matter that does not find adequate support in the specification.

In response, Applicants first respectfully point out that the above noted subject matter that forms the basis of the examiner's position is in fact disclosed at page 22, lines 4-8 as indicated in Applicants' previously filed response. Nevertheless, and without conceding the correctness of the Examiner's positions either with respect to written description or enablement, but to expedite allowance of the subject application. Applicants have amended claims 1, 41, 55, and 57, without prejudice, to remove reference to variants. Accordingly, claims 1, 41, 55, and 57 and those depending therefrom, now recite only subject matter that the Examiner has indicated is enabled by the specification. Moreover, the language that formed the basis of the Examiner's written description rejection no longer appears in the claims. Therefore, Applicants believe that the

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above-noted claim amendments fully overcome the Examiner's rejections under 35 U.S.C. §112, first paragraph, and thus, respectfully request that the Examiner reconsider and withdraw the rejection.

Examiner's rejections under 35 U.S.C. §112, second paragraph

The Examiner maintained the rejection of claim 1 under 35 U.S.C. §112, second paragraph, as allegedly indefinite in its recitation of the term "under conditions" for inducing expression of the polynucleotide and presentation of the passenger peptide or polypeptide. The Examiner has cited several references and asserted that these references suggest that different gram-negative organisms might require different conditions when used in the claimed process.

In response, Applicants respectfully traverse this rejection. Applicants maintain that one of ordinary skill in the art would readily recognize from the specification what conditions are necessary to carry out the process defined in claim 1. Applicants note that the legend of Figure 5 (at pages 14-15) describes the culture of *E.coli* cells on LB (Luria Bertani) agar in the presence of an antibiotic, which is a standard procedure for culturing bacteria. (See attached copy of excerpt from the well known manual on molecular cloning by Sambrook, et al.). The Maurer reference, cited by the Examiner, also employs this method. The culture of *E.coli* in Luria broth agar as cited by the Examiner (in the Hickman reference) is also a standard protocol. Furthermore, a person skilled in the art knows that the *Rickettsia* species can only be cultured on eukaryotic cells. L-929 is a fibroblast cell line known since 1943 (see enclosed DSMZ data sheet). A 5% CO₂ humidified atmosphere at 34°C is a standard condition for eukaryotic cells not limited to

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fibroblast culture. Accordingly, Applicants believe that the examples provided by the Examiner with respect to culture conditions in fact confirm Applicants' position that the conditions under which the present invention is performed can be readily determined and understood by one of ordinary skill in the art in view of the teachings set forth in the specification. Therefore, Applicants maintain that claim 1 as amended is not indefinite and thus, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 1 under 35 U.S.C. §112, second paragraph.

The Examiner also rejected claims 15 and 19 under 35 U.S.C. §112, second paragraph, as allegedly being unclear in their recitation of libraries of variant passenger peptides or polypeptides. The Examiner has indicated that it is unclear how such libraries are produced given that claim 1 is directed to a process of presenting one peptide or polypeptide on the surface of a host.

In response, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicants have amended claim 15 for clarity to recite that each host cell expresses one passenger variant. Applicants believe that this amendment to claim 15 fully overcomes the Examiner's concerns and that claims 15 and 19, as amended, are not indefinite. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 15 and 19 under 35 U.S.C. §112, second paragraph.

Examiner's claim objection

The Examiner objected to claim 1, asserting that the claim recites plural forms of the

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terms "peptide" and "polypeptide," even though the process is directed to presenting one passenger peptide or polypeptide on the surface of a gram-negative bacteria.

In response, Applicants respectfully point out that the correction the Examiner is seeking to overcome this objection was in fact made in the previously filed Amendment. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this objection.

In view of the above remarks and amendments, Applicants believe that all of the Examiner's rejections and objections set forth in the November 3, 2004 Final Office Action have been fully overcome and that the present application is in condition for allowance. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,



Date: March 3, 2005

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Attachments: Sambrook, et al. excerpt (1 pg.)
DSMZ data sheet (1pg.)